Remarks

Claims 1-7 and 9-14 were pending in this case. Claims 1-7 and 9-14 were rejected.

Non-statutory provisional double patenting rejection

Claims 1, 2, 4, 7 and 11 stand provisionally rejected on the ground of non-statutory obviousness-type double patenting as allegedly unpatentable over Claim 30 of U.S. Patent No. 7,001,920 and Claim 41 of U.S. Patent No. 6,673,838. Without addressing the merit of the rejection, in order to facilitate the prosecution of the current case, Applicants acknowledge that a terminal disclaimer may be used to overcome a rejection for non-statutory double patenting upon a finding that all other rejections have been overcome.

Claim rejections under 35 U.S.C. § 112, first paragraph

Claims 1-7 and 9-14 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. It is maintained into the Advisory Action that the specification allegedly does not teach a method of treating bulimia nervosa in a mammal. Finally, it is alleged in the Advisory Action that Applicants have not shown that the presently disclosed compounds are all antidepressants.

Applicants respectfully traverse the rejection under 35 U.S.C. § 112, first paragraph.

To satisfy the written description requirement under 35 U.S.C § 112, first paragraph, the specification should contain a written description of the invention and the manner and process of making and of using it, in such a way, to enable the person of ordinary skill in the art to practice the invention without undue experimentation.
Applicants respectfully maintain that one skilled in the art, with Applicants disclosure before him or her, would be able to practice the claimed invention without undue experimentation.
The present application incorporates by reference, U.S. Patent No. 4,535,186 (Husbands *et al.*), which discloses (see column 1) that the compounds of the presently claimed formula, substituted phenethylamine derivatives, are central nervous system antidepressants.
As acknowledged in the Office Action, the present specification does teach a method of treating obesity by administering venlafaxine. As described in the present specification (page 8, lines 21-24), the administered dosages of venlafaxine were well within the dosage range prescribed for the use of venlafaxine to treat depression.

It is known in the art that antidepressants treat bulimia. For example Pope *et al.* (cited in the Office Action) teach the use of a variety of antidepressants for the treatment of bulimia.
In view of the above, Applicants submit that the presently claimed invention clearly satisfies the written description requirement and respectfully request the withdrawal of the rejection of claims 1-7 and 9-14 under 35 U.S.C. § 112, first paragraph.

Claim rejections under 35 U.S.C. § 103

Claims 1-5, 7 and 9-13

Claims 1-5, 7 and 9-13 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Pope *et al.* (J. Clin. Psychiatry, July 1985, 339-34560) (hereinafter "Pope *et al.*") in view of Schweizer *et al.* (J. of Clin. Psychopharmacology, 1991, 233-36) (hereinafter "Schweizer *et al.*") because it was maintained that one skilled in the art would have been motivated to substitute venlafaxine for another antidepressant in a method of treating bulimia.

Applicants respectfully traverse the rejections under 35 U.S.C. § 103(a).

Pope *et al.* describe the use of a number of known antidepressants from a variety of drug classes for the treatment of bulimia. The compounds administered by Pope *et al.* are tricyclic antidepressants (imipramine, amitriptyline), or monoamine oxidase inhibitors (phenelzine), dopamine reuptake inhibitors (nomifensine) or anticonvulsants/mood stabilizers (sodium valproate).
Pope *et al.* specifically refer to phenelzine, known as a potent monoamine oxidase enzyme (MAO) inhibitor. Phenelzine is used to treat certain types of serious depression and severe depression complicated by severe anxiety that do not respond to other antidepressant drugs. However, unlike the claimed compound, venlafaxine, none of the drugs discussed in Pope *et al.* are serotonin reuptake inhibitors, norepinephrine reuptake inhibitors or combined norepinephrine and serotonin uptake inhibitors (SNRIs). The compounds discussed in Pope *et al.* act by different mechanisms than the compounds of the presently claimed method. MAO inhibitors and serotonin reuptake inhibitors, norepinephrine reuptake inhibitors or combined norepinephrine and serotonin uptake inhibitors (SNRIs) have very different mechanisms of action acting on different receptors. As stated in the Office Action dated December 23, 2008, "the treatment of a disease is notoriously unpredictable unless correlation has been conclusively verified".

Since the presently claimed method defines the administration of compounds neither taught nor suggested by Pope *et al.* for the treatment of bulimia, the reference provides no reasonable expectation of success for the claimed method.

Schweizer *et al.* refer to the first placebo-controlled trial of venlafaxine in the treatment of major depression. The teachings of Schweizer *et al.* do not overcome the deficiencies of Pope *et al.* In view of the foregoing, Applicants maintain that claims 1-5, 7 and 9-13 are not rendered obvious in light of Pope *et al.* in view of Schweizer *et al.* and respectfully request that the rejection be withdrawn.

Claim 6

Claim 6 stands rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Pope *et al.* in view of Schweizer *et al.* and further in view of Wang *et al.* (Chirality, 1992, 4(2), 84-90) (hereinafter "Wang *et al.*").

Claim 6 was also rejected under 35 U.S.C. § 103(a) as being unpatentable over Pope *et al.* in view of Edgren *et al.* and further in view of Wang *et al.*

Both rejections under 35 U.S.C. §103(a) will be addressed together in view of their similar nature.

Claim 6 defines the localized positions of substituents R_5 and R_6 on the phenyl ring relative to the point of attachment and does not relate to stereoselectivity.

The Office Action states that it would have been obvious for the person of skill in the art to prepare and separate selective stereoisomers of venlafaxine for its use in treating bulimia nervosa.

Applicants apply their above statements with regards to Pope *et al.*

Wang *et al.* teach a method for the quantitation of the enantiomers of venlafaxine in plasma. The compounds cited by Wang *et al.* are enantiomers of venlafaxine and the different metabolites of venlafaxine are used for reference purposes. None of these compounds have substituents at the meta position. Wang *et al.* do not teach or suggest the use of venlafaxine stereoisomers in the treatment of bulimia nervosa. Nothing in Wang *et al.* supplies the deficiencies of Pope *et al.* Furthermore, Applicants do not claim stereoisomers of venlafaxine for the treatment of bulimia nervosa. Accordingly, this rejection is moot.

Edgren *et al.* teach an osmotic pump dosage form of venlafaxine.

In view of the above, Applicants respectfully request the withdrawal of the rejection of claim 6 under 35 U.S.C. § 103(a) over Pope *et al.* in view of Schweizer *et al.* and further in view of Wang *et al.* and under 35 U.S.C. § 103(a) over Pope *et al.* in view of Edgren *et al.* and further in view of Wang *et al.*

Claims 1-5, 7 and 9-14

Claims 1-5, 7 and 9-14 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Pope *et al.* in view of Edgren *et al.* Applicants respectfully traverse this rejection. Nothing in Edgren *et al.* would motivate the person of ordinary skill in the art to administer venlafaxine for the treatment of bulimia, and as stated above, Pope *et al.* do not teach or suggest the use of the claimed compounds for treating bulimia.

Accordingly, Applicants respectfully request that the rejections under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

In view of the foregoing discussion, applicants submit that the present application is in condition for allowance. Reconsideration and allowance are respectfully requested.

If a telephone conference would advance prosecution of this application, the Examiner is invited to telephone the undersigned at .

Respectfully submitted,

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